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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/029,630	12/21/2001	Birgit Jung	1/1179	5076

28501 7590 03/05/2004

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EXAMINER

BELYAVSKYI, MICHAEL A

ART UNIT PAPER NUMBER

1644

DATE MAILED: 03/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/029,630	<b>Applicant(s)</b> JUNG ET AL.	
	<b>Examiner</b> Michail A Belyavskiy	<b>Art Unit</b> 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-41 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                            | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____   |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)        | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

*Claims 1-41 are pending.*

### ***Restriction Requirement***

- 1 Restriction to one of the following inventions is required under 35 U.S.C. § 121:
  - I. Claims 1 –3, 5, 6, 7 and 9-14 , drawn to a method for determining whether a substance is an activator or an inhibitor of a function of a UDD protein, wherein UDD-protein consists of SEQ ID NO:4 and wherein the inhibition or activation is measured *directly* and wherein the method is performed using *a cellular system*, classified in Class 435, subclass 41; Class 530, subclasses 300 and 350.
  - II. Claims 1 –3, 5, 6, 7 and 9-14 , drawn to a method for determining whether a substance is an activator or an inhibitor of a function of a UDD protein, wherein UDD-protein consists of SEQ ID NO:8 and wherein the inhibition or activation is measured *directly* and wherein the method is performed using *a cellular system*, classified in Class 435, subclass 41; Class 530, subclasses 300 and 350.
  - III. Claims 1, 2, 4, 5, 6, 7 and 9-14 , drawn to a method for determining whether a substance is an activator or an inhibitor of a function of a UDD protein wherein UDD-protein consists of SEQ ID NO:4 and wherein the inhibition or activation is measured *indirectly* and wherein the method is performed using *a cellular system*, classified in Class 435, subclass 41; Class 530, subclasses 300 and 350.
  - IV. Claims 1, 2, 4, 5, 6, 7 and 9-14 , drawn to a method for determining whether a substance is an activator or an inhibitor of a function of a UDD protein wherein UDD-protein consists of SEQ ID NO:8 and wherein the inhibition or activation is measured *indirectly* and wherein the method is performed using *a cellular system*, classified in Class 435, subclass 41; Class 530, subclasses 300 and 350.
  - V. Claims 1 –3, 5, 6, 8 and 9-14 , drawn to a method for determining whether a substance is an activator or an inhibitor of a function of a UDD protein wherein UDD-protein consists of SEQ ID NO:4 and wherein the inhibition or activation is measured *directly* and wherein the method is performed using *a cell-free system*, classified in Class 530, subclasses 300 and 350.

- VI. Claims 1 –3, 5, 6, 8 and 9-14 , drawn to a method for determining whether a substance is an activator or an inhibitor of a function of a UDD protein wherein UDD-protein consists of SEQ ID NO:8 and wherein the inhibition or activation is measured *directly* and wherein the method is performed using a *cell-free system*, classified in Class 530, subclasses 300 and 350.
- VII. Claims 1, 2, 4, 5, 6, 8 and 9-14 , drawn to a method for determining whether a substance is an activator or an inhibitor of a function of a UDD protein wherein UDD-protein consists of SEQ ID NO:4 and wherein the inhibition or activation is measured *indirectly* and wherein the method is performed using a *cell-free system*, classified in Class 530, subclasses 300 and 350.
- VIII. Claims 1, 2, 4, 5, 6, 8 and 9-14 , drawn to a method for determining whether a substance is an activator or an inhibitor of a function of a UDD protein wherein UDD-protein consists of SEQ ID NO:8 and wherein the inhibition or activation is measured *indirectly* and wherein the method is performed using a *cell-free system*, classified in Class 530, subclasses 300 and 350.
- IX. Claims 15-22 and 25 drawn to a method for determining an expression levels of the UDD-protein, wherein UDD-protein consists of SEQ ID NO:4 classified in Class 435, subclass 325; Class 530, subclass 350.
- X. Claims 15-22 and 25 drawn to a method for determining an expression levels of the UDD-protein, wherein UDD-protein consists of SEQ ID NO:8 classified in Class 435, subclass 325; Class 530, subclass 350.
- XI. Claims 23-24, drawn to a method for diagnosing or monitoring a chronic inflammatory airway disease, classified in Class 435, subclass 325; Class 530, subclass 350.
- XII. Claims 26-32, drawn to a substance determined to be an activator of a UDD protein, and pharmaceutical composition comprising said substance, classified in Class 530, subclasses 300 and 350 and Class 424, subclass 184.1.
- XIII. Claims 26-32, drawn to a substance determined to be an inhibitor of a UDD protein, and pharmaceutical composition comprising said substance, classified in Class 530, subclasses 300 and 350 and Class 424, subclass 184.1.

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- XIV. Claims 33-37, drawn to a method for treating a chronic inflammatory airway disease comprising administering an effective amount of activator of a UDD-protein, classified in Class 424, subclass 184.1.
- XV. Claims 33-37, drawn to a method for treating a chronic inflammatory airway disease comprising administering an effective amount of inhibitor of a UDD-protein, classified in Class 424, subclass 184.1.
- XVI. Claims 38-41, drawn to a method for selectively modulating a UDD-protein in a macrophages comprising administering an activator of a UDD-protein, classified in Class 424, subclass 184.1 and Class 435 subclass 375.
- XVII. Claims 38-41, drawn to a method for selectively modulating a UDD-protein in a macrophages comprising administering an inhibitor of a UDD-protein, classified in Class 424, subclass 184.1 and Class 435 subclass 375.

2. Groups I- XI and XIV- XVII are different methods. These inventions are different with respect to ingredients, method steps, and endpoints which require non-coextensive searches ; therefore, each method is patentably distinct.

3. Groups XII and XIII are different products. These invention are differ with respect to their structures and physicochemical properties, which require non-coextensive searches; therefore each product is patentably distinct.

4. Groups (XII and XIII) and (XIV- XVII) are related as product and process of using. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product, inhibitor or activator of UDD-protein can be used for crystallography.

5. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Moreover, a prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention. Therefore restriction for examination purposes as indicated is proper.

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### **Species Election**

6. Applicant is further required under 35 USC 121 (1) to elect a single disclosed species to which the claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

7. If Group XI is elected, applicant is required to elect a specific method for diagnosing or monitoring a chronic inflammatory airway disease, wherein a specific chronic inflammatory airway disease is selected from the group recited in claim 24.

These species are distinct because a specific method for diagnosing or monitoring a chronic inflammatory airway disease, wherein a specific chronic inflammatory airway disease is selected from the group recited in claim 24 differ in etiologies and therapeutic endpoints of pathological conditions; thus each condition represents patentably distinct subject matter.

8. If Groups XII or XIII is elected, applicant is required to elect a specific chronic inflammatory airway disease, wherein a specific chronic inflammatory airway disease is selected from the group recited in claim 30.

These species are distinct because a specific chronic inflammatory airway disease, wherein a specific chronic inflammatory airway disease is selected from the group recited in claim 30 differ in etiologies and therapeutic endpoints of pathological conditions; thus each condition represents patentably distinct subject matter.

9. If Groups XVI or XVII is elected, applicant is required to elect a specific method for selectively modulating a UDD-protein in a macrophages wherein a specific chronic inflammatory airway disease is selected from the group recited in claim 40.

These species are distinct because a specific method for selectively modulating a UDD-protein in a macrophages wherein a specific chronic inflammatory airway disease is selected from the group recited in claim 40 differ in etiologies and therapeutic endpoints of pathological conditions; thus each condition represents patentably distinct subject matter.

10. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

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Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.


11. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

A telephone call was made to Susan Pocchiari on 01/16/04 to request an oral election to the above restriction requirement, but did not result in an election being made.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskiy whose telephone number is 571/ 272-0840. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571/ 272-0841. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is 703/872-9306.

Michail Belyavskiy, Ph.D.  
Patent Examiner  
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January 29, 2004

  
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